DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 5, 2015

Stryker
Ms. Julie Schoell M.S., RAC
Staff Regulatory Affairs Specialist
750 Trade Centre Way - Suite 200
Portage, Michigan 49009

Re: K142568
Trade/Device Name: Stryker MEDPOR TITAN 3D Orbital Floor Implant
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: April 10, 2015
Received: April 13, 2015

Dear Ms. Schoell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142568

Device Name
Stryker MEDPOR TITAN® 3D Orbital Floor Implant

Indications for Use *(Describe)*
The MEDPOR TITAN® 3D Orbital Floor Implant is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in patients 15 years of age and older.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5. 510(k) Summary – K142568

This section provides a summary of 510(k) information in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

510(k) Owner:	Stryker Leibinger GmbH& Co. KG Boetzinger Strasse 41 D-79111 Freiburg, Germany
Submitter/ Contact Person:	Julie Schoell, M.S., RAC Staff Regulatory Affairs Specialist Stryker Craniomaxillofacial 750 Trade Centre Way Portage, MI 49002 Phone: 269-389-3419 Fax: 877-648-7114
Registration Number:	8010177
Date prepared:	April 29, 2015

II. DEVICE

Trade Name:	Stryker MEDPOR TITAN® 3D Orbital Floor Implant
Common or Usual name:	Plate, Bone
Classification name:	Bone Plate (21 CFR 872.4760)
Regulatory Class:	Class II
Product Code:	JEY

III. PREDICATE DEVICE

Predicate Device: Stryker Universal Orbital Floor System – K133461

Reference Device: MEDPOR Craniofacial Implants with Embedded Titanium Mesh – K040364

IV. DEVICE DESCRIPTION

The MEDPOR TITAN® 3D Orbital Floor Implants are comprised of a pre-bent titanium mesh embedded within a MEDPOR porous polyethylene sheet. The porous side allows tissue ingrowth while a nonporous Barrier sheet on the orbit facing side does not allow tissue ingrowth. The pre-bent shape approximates the shape and dimensions of the average normal orbital floor and medial wall (in order to facilitate the operative goal of restoring normal [pre-traumatic] orbital volume as accurately as possible). The pre-bent MEDPOR titanium plates are available in a small (L=32mm W=35mm, H=13mm) and a large size (L=36mm, W=37mm, H=17mm) along with left and right configurations. The implants can be trimmed and contoured to fit the specific needs of the patient.

The implants are designed based on an average anatomical model of CT-scan data taken from 300 subjects (92% Caucasian). The metadata of the 300 subjects that have been included in the generation of the average anatomical model is listed in Table 1. The selected scans were obtained from healthy subjects without any deformation of the bony orbital structures.

TABLE 1: META DATA OF THE 300 CT SCANS

Age [years]		Gender		Ethnic	
10-19	18	f	122	ca	276
20-29	19	m	178	me	3
30-39	20			xx	21
40-49	28				
50-59	36				
60-69	56				
70-79	72				
80-89	44				
90-99	6				

Age: 297 scans: age 15-95, 1 scan: age 14, 1 scan: 11, 1 scan: unknown; average age: 59 years;

Gender: 122 female (f) and 178 male (m);

Ethnic Group: 276 Caucasians (ca), 3 Middle-East (me), 21 unknown (xx)

The associated accessories include the following previously cleared devices:

- Adjustable-width globe retractor
- Plate holding forceps
- Stryker screws and accessories

The Subject device will be provided sterile, and is intended for single use only. The plate holding forceps and adjustable-width globe retractor are provided non-sterile and are reusable.

V. INDICATIONS FOR USE

The MEDPOR TITAN® 3D Orbital Floor Implant is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in patients 15 years of age and older.

TABLE 2: COMPARISON OF INDICATIONS FOR USE

	Subject Device	Predicate Device – K133461	Reference Device – K040364
Indications for Use	The MEDPOR TITAN® 3D Orbital Floor Implant is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in patients 15 years of age and older.	The Stryker Universal Orbital Floor System is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in patients 15 years of age and older.	MEDPOR Biomaterial with Embedded Titanium Mesh Implants are intended for non-weight bearing applications of craniofacial reconstruction/cosmetic surgery and repair of craniofacial trauma.

The Indications for Use statement for the MEDPOR TITAN 3D Orbital Floor Implant is identical to the predicate device Stryker Universal Orbital Floor System.

The Indications for Use statement for the MEDPOR TITAN 3D Orbital Floor Implant is not identical to the reference device MEDPOR Craniofacial Implants with Embedded Titanium Mesh Implants; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. The MEDPOR Craniofacial Implants with Embedded Titanium Mesh are indicated for a use in a range of anatomic areas for a variety of surgical applications. The Indications for use of the MEDPOR TITAN 3D Orbital Floor Implant falls within the scope of the broader Indications for Use statement of the reference device. The difference in the Indications statement for the proposed device in comparison to the reference device does not constitute a new intended use. Both the subject and predicate device have

the same intended use for the reconstruction of the floor and/or medial wall of the orbit.

A review of the literature was performed to identify relevant clinical literature to represent applicable data on the performance of the Stryker MEDPOR TITAN 3D Orbital Floor Implant in the use of the orbital floor. Results of the data demonstrates the absences of unreasonable risk of illness or injury associated with use of the Stryker MEDPOR TITAN 3D Orbital Floor Implant for its intended uses and conditions of use; in this case, in a pediatric sub-population 15 to 21 years of age and for reconstruction of the craniofacial skeleton, of which the orbital floor and/or wall is indicated.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The MEDPOR TITAN 3D Orbital Floor Implant is compared to its predicate devices for substantial equivalence based on the following criteria:

A. Principle of Operation
B. Technological Characteristics

A. Principle of Operation

The basic operational principle of the Subject device, as well as the Predicate device, is to reconstruct the orbital floor and/or medial wall. The fixation method of both the Subject device and the Predicate device is with screws inserted through dedicated screw holes. Both the Subject device as well as the Predicate device can be trimmed and contoured to fit the specific needs of the patient. The Subject device and the Predicate device are permanent implants and have the same craniofacial/orbital area of application.

B. Technological and Operational Characteristics

At a high level, the Subject device and Predicate device are based on the following technological elements:

- Same operating principle: reconstruct the orbital floor and/or medial wall
- Same mode of fixation: plate fixation with screws inserted through dedicated screw holes
- Same patient contacting surface: orbital floor and wall
- Same area of contact and contact duration (tissue/bone/greater than 30 days)

- Similar material: while the MEDPOR Craniofacial Implants with Embedded Titanium Mesh reference device has the same material, the Stryker Universal Orbital Floor System is provided only in titanium.
- Similar design: while the Stryker Universal Orbital Floor System has a pre-bent shape based on the same average anatomical model, the MEDPOR Craniofacial Implants with Embedded Titanium Mesh are provided in a 2D, non-bent shape.
- Similar sizes and shapes compared to the Predicate device
- The MEDPOR TITAN 3D Orbital Floor Implant is provided sterile. While the MEDPOR Craniofacial Implants with Embedded Titanium Mesh reference device is provided sterile, the Stryker Universal Orbital Floor System is provided non-sterile.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the MEDPOR TITAN 3D Orbital Floor was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "*Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*,'" May 1, 1995, and International Standard ISO 10993-1 "*Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process*," as recognized by FDA. The testing included cytotoxicity testing.

The cytotoxicity testing was performed using DIN EN 10993-5:2009, Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity. The tests supported the biocompatibility of the device.

The MEDPOR TITAN 3D Orbital Floor Implant is considered a permanent implant, tissue contacting greater than 30 days. The implant is made from a combination of titanium mesh embedded within a MEDPOR porous polyethylene sheet with a nonporous Barrier on one side, the same as the Predicate devices. The titanium conforms to ASTM F67 for chemical composition. The same manufacturing processes and identical materials are used in the predicate devices and the Subject device.

Performance Bench Testing

The following performance bench tests were completed.

- Transportation testing
- End user testing
- Packaging assessment
- Bending assessment
- Trimming assessment
- Stability test (globe support)
- Sharp edge test

The Subject device met all pre-defined acceptance criteria and, in tests where it was compared to either the predicate or reference device, was found to not represent a new worst case. Overall, the results of the performance bench tests support the substantial equivalence of the Subject device.

Animal Testing

Animal testing was not required as a basis for substantial equivalence.

Clinical Testing

Clinical testing was not required as a basis for substantial equivalence.

VIII. CONCLUSIONS

The results of the non-clinical data demonstrate the MEDPOR TITAN 3D Orbital Floor Implants will perform as intended in the specified use conditions. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the information included in this submission supports substantial equivalence.